

SEALED
FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
NORTHERN DIVISION

OCT 23 2017

UNITED STATES OF AMERICA
ex rel. NICK GRIMALDI, D.O.

STATE OF TENNESSEE
ex rel. NICK GRIMALDI, D.O.

Plaintiff-Relator,

v.

JOE CHADWICK WHITE, JOHN DOE
INVESTORS 1-1000, and
JOHN DOE COMPANIES 1-1000,

Defendants.

Clerk, U. S. District Court
Eastern District of Tennessee
At Chattanooga

Case No.

3:17-CV-463
JURY TRIAL DEMANDED
FILED UNDER SEAL

Judge Reeves
Judge Guyton

COMPLAINT

Relator Nick Grimaldi, D.O., on behalf of himself, the United States of America, and the State of Tennessee, brings this action under 31 U.S.C. §§ 3729-3732 ("False Claims Act") to recover all damages, penalties, and other remedies established by the False Claims Act. By and through his counsel, Relator hereby files this False Claims Act Complaint and Demand for Jury Trial ("Complaint") against Defendant Joe White and John Doe Companies ("Defendants"), and alleges as follows:

JURISDICTION AND VENUE

1. This action arises under the False Claims Act, as amended, 31 U.S.C. §§ 3729 *et seq.* and the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.* (collectively, the "False Claims Acts").

2. This court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 31 U.S.C. § 3732(b), and 28 U.S.C. § 1345.

3. This court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a) in that Defendants do or transact business in this jurisdiction and violations of the False Claims Acts described herein were carried out in this district.

4. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and under 31 U.S.C. § 3732(a) because Defendants do or transact business in this jurisdiction and violations of the False Claims Acts described herein were carried out in this district.

COMPLIANCE WITH PROCEDURAL REQUIREMENTS

5. As required by the federal FCA, 31 U.S.C. § 3730(b)(2), Relator has provided to the Attorney General of the United States and the United States Attorney for the Eastern District of Tennessee a statement of all material evidence and information related to the Complaint (“Disclosure Statement”).

6. The Disclosure Statement is supported by material evidence known to Relator at the time of his filing, establishing the existence of Defendants’ false claims.

7. The Disclosure Statement includes attorney-client communications and work product of Relator’s attorneys and is submitted to the Attorney General of the United States and the United States Attorney for the Eastern District of Tennessee in their capacities as potential co-counsel in this litigation; therefore, the Disclosure

Statement is confidential and protected by the joint prosecutorial privilege.

PARTIES

8. Defendant Joe White, by and through his various companies such as MedX Surgical, LLC and SurgiTenn, is a salesman of implantable medical devices.

9. In addition to being a distributor for medical device manufacturers (e.g., Tornier, Aesculap, Precision Spine), White markets, creates, and invests in physician-owned distributorships (PODs) that violate the Anti-Kickback Statute.

10. White resides at and runs his companies from 2831 Blue Herron Way, Louisville, TN 37777.

11. Defendants John Doe Investors are the individuals who have directly or indirectly invested in the PODs set up by Joe White that violate the Anti-Kickback Statute and that thereby cause false claims to be submitted to the Government.

12. Defendants John Doe Companies are the investing LLCs and holding companies formed for the purposes of advancing the POD schemes.

13. Relator Nick Grimaldi, D.O. is an orthopedic surgeon and owner/operator of East Tennessee Spine and Orthopaedic Specialists, P.C. (ETSOS) in Morristown, TN.

FEDERALLY FUNDED HEALTHCARE PROGRAMS

14. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, establishes the Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program. The Secretary of Health and Human Services (“HHS”)

administers the Medicare Program through the Centers for Medicare and Medicaid Services (“CMS”).

15. In order to receive Medicare funds, enrolled providers are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the states.

16. Among the rules and regulations which enrolled providers agree to follow are to: (a) bill Medicare for only those covered services which are medically necessary; (b) not bill Medicare for any services or items which were not performed or delivered in accordance with all applicable policies, nor submit false or inaccurate information relating to provider costs or services; (c) not engage in any act or omission that constitutes or results in over-utilization of services; (d) comply with state and federal statutes, policies and regulations applicable to the Medicare Program; and (e) not engage in any illegal activities related to the furnishing of services to recipients.

17. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* establishes Medicaid, a federally assisted grant program for the States. Medicaid enables the States to provide medical assistance and related services to needy individuals. CMS administers Medicaid on the federal level. Within broad federal rules, however, each state decides who is eligible for Medicaid, the services covered, payment levels for services and administrative and operational procedures.

18. At all times relevant to this Complaint, the United States provided funds to the States through the Medicaid program pursuant to Title XIX of the Social

Security Act, 42 U.S.C. §§ 1396 *et seq.* Enrolled providers of medical services to Medicaid recipients are eligible for payment for covered medical services under the provisions of Title XIX of the 1965 Amendments to the Federal Social Security Act.

19. By becoming a participating provider in Medicaid, enrolled providers agree to abide by the rules, regulations, policies and procedures governing claims for payment, and to keep and allow access to records and information as required by Medicaid. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees, and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the State.

20. 42 C.F.R. §§ 455 *et seq.*, expressly states that a provider must certify that it is in compliance with all federal and state statutes and regulations in order to receive payment from Medicaid.

21. Joe White's PODs distribute equipment that is implanted in patients who are enrolled in Medicare, as well as other Government-funded programs including, but not limited to, Medicare Advantage Plans, Medicaid, TRICARE, CHAMPVA, and the Federal Employees Health Benefits Program (collectively referred to herein as "Federal Insurance"), for which Federal Insurance is billed.

THE ANTI-KICKBACK STATUTE

22. The Anti-Kickback Statute (AKS) prohibits the knowing and willful offering, paying, solicitation, or receipt of remuneration in cash or in kind to induce or reward patient referrals or the generation of business involving any item or service

payable by Federal Insurance, including Medicaid, Medicare, and Tricare. 42 U.S.C. §1320a-7b.

23. Pursuant to the AKS, a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. 42 U.S.C. § 1320a-7b(g).

24. Compliance with the Anti-Kickback Statute is material to claims for payment from Government Insurance pursuant to the CMS-855O Medicare Enrollment Application, which conditions payment on compliance with the statute, and case law that has determined that violations of the Anti-Kickback Statute are material. *See U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 2017 U.S. Dist. LEXIS 138722, at *9 (D.S.C. Aug. 27, 2017) (applying common sense and weight of authority).

25. By violating the AKS, Joe White causes false claims to be submitted for reimbursement to Federal Insurance.

SPECIFIC ALLEGATIONS

26. A POD derives revenues from selling implantable medical devices ordered by its physician-owners for use in procedures the physician-owners perform on their own patients.

27. In a “physician distributor” model, the POD acts as a product distributor that buys devices from manufacturers, and then resells them to the hospitals where the physician-investors refer their patients for procedures.

28. Because they incentivize the physician-owners to prescribe their own products to increase profits, HHS-OIG has found that PODs have the potential to

“produce substantial fraud and abuse risk and pose dangers to patient safety.”

HHS-OIG Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013).

29. According to HHS-OIG, “PODs that exhibit... questionable features potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices.”

30. Accordingly, HHS-OIG believes that PODs are “inherently suspect under the anti-kickback statute.”

31. Joe White develops and invests, and solicits others to invest, in PODs that violate the AKS.

32. White tries to avoid liability under the AKS by creating a holding company to own the POD. The holding company, in turn, is owned by LLCs, which are owned by himself and the physician investors. Under this model, the physicians do not directly own the POD.

33. In fact, because the investors in the holding company are all LLCs, each investor in the POD does not know who the other investors are (excepting Joe White).

34. In addition to the POD structure, and in an even more flagrant violation of the AKS, the holding company pays the investors based on a volume of referrals.

35. Because the physicians have an ownership interest in the holding company, these self-referrals and payoffs violate the Stark Law, 42 U.S.C. § 1395nn.

36. White tried to convince Relator to invest in a POD that sells “total joints”, which procedures are ultimately billed to Federal Insurance under CPT Codes 27447 (knees), 27130 (hips), and 23472 (shoulders).

37. White also talked to Relator and his PA about investing in a POD for spinal hardware for cervical fusions, which procedures are billed under CPT Code 22845.

38. White first approached the doctors at ETSOS in 2011, but Dr. Grimaldi had concerns about the legality of the POD, and so the discussions went no further.

39. In June 2014, Joe White returned to ETSOS.

40. Joe White hosted a lunch for the ETSOS office, but Dr. Grimaldi was unable to attend. When Dr. Grimaldi arrived at the office at the end of the lunch, White pulled him aside and told him that he wanted to do a POD with him. Dr. Grimaldi agreed to meet with White on June 12, 2014.

41. During their meeting, Joe White explained to Dr. Grimaldi how he could invest in a POD without the hospitals or federal government learning about it by having a separate holding company handle all of the invoicing and distributions and by investing in the POD through an LLC.

42. Because the PODs do not market their products to anyone other than their own investor-physicians, their profits are derived entirely from the doctors in the POD using the POD's products.

43. To induce Dr. Grimaldi to join the POD, White asserted that "everyone is targeting between sixty and eighty thousand a month in sales" and that if all investors met their targets, Dr. Grimaldi would essentially double his profits overnight.

44. This payment structure incentivizes the doctors in the PODs to utilize the POD's products instead of the implants they would otherwise recommend due to safety, reliability, or clinical appropriateness. In fact, White explained that if certain doctors failed to carry their weight by performing enough procedures with the product to earn their share, the POD would dissolve and reform without those doctors as investors.

45. Moreover, White assured Dr. Grimaldi that there was no financial risk to the investors because the POD does not pay in advance for an inventory of products; it simply collects a fee after they are already sold and implanted.

46. White offered Dr. Grimaldi a 40% share in the POD and Dr. Grimaldi's PA a 15% share in the POD.

47. White suggested that the kickbacks could be laundered by paying bogus "consulting fees"; paying bogus rent for space in the ETSOS building, the size of which could vary from month-to-month; and buying property to immediately re-sell to the investor for \$1.

48. White bragged that he had been setting up PODs like this for three years, all over the country, and had never been caught, even though the federal government was shutting down PODs for healthcare fraud and going after kickbacks.

49. On September 10, 2014, Relator spoke with a distribution representative who told him that Joe White had admitted to him that he had paid cash to doctors for using his products.

50. All claims submitted to Federal Insurance for procedures tainted by unlawful referrals and/or kickbacks in violation of the AKS or Stark Law are false and in violation of the False Claims Act.

COUNT I
VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)

51. Relator hereby incorporates and realleges herein the allegations set forth in the above paragraphs.

52. As set forth above, Defendants, individually and by and through their agents, officers, and employees, knowingly presented or caused to be presented numerous false or fraudulent claims for payment or approval, in violation of the federal FCA, 31 U.S.C. § 3729(a)(1)(A).

53. Due to Defendants' conduct, the United States Government has suffered substantial monetary damages.

54. The United States is entitled to treble damages based upon the amount of damage sustained by the United States as a result of the aforementioned violations of the federal FCA, 31 U.S.C §§ 3729-3733, in an amount that will be proven at trial.

55. Relator is also entitled to reasonable attorneys' fees and costs, pursuant to 31 U.S.C. § 3730(d)(1).

COUNT II
VIOLATION OF TENNESSEE CODE ANNOTATED § 71-5-182 –
TENNESSEE MEDICAID FALSE CLAIMS ACT

56. Relator hereby incorporates and realleges herein the allegations set forth in the above paragraphs.

57. As set forth above, Defendants, individually and by and through their agents, officers, and employees, knowingly presented, or caused to be presented to the Tennessee Medicaid program numerous false or fraudulent claims for payment or approval, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

58. Due to Defendants' conduct, the State of Tennessee has suffered substantial monetary damages.

59. The State of Tennessee is entitled to treble damages based upon the amount of damage sustained by the State of Tennessee as a result of the aforementioned violations of the Tenn. Code Ann. § 71-5-182(a), an amount that will be proven at trial.

60. The State of Tennessee is entitled to a civil penalty as required by Tenn. Code Ann. § 71-5-182(a) for each of the fraudulent claims.

61. Relator is also entitled to reasonable expenses which the court finds to have been necessarily incurred and reasonable attorneys' fees and costs, pursuant to Tenn. Code Ann. § 71-5-183(d).

PRAYER FOR RELIEF

WHEREFORE, Relator Nick Grimaldi prays for judgment against Defendants:

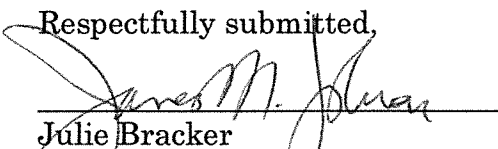
- (a) awarding the United States treble damages sustained by it for each of the false claims;
- (b) awarding the United States the maximum civil penalty for each of the false claims and statements;
- (c) awarding the State of Tennessee treble damages sustained by it for each of the false claims;
- (d) awarding the State of Tennessee civil penalties for each of the false claims;
- (e) awarding Relator thirty percent (30%) of the proceeds of this action and any alternate remedy or the settlement of any such claim;
- (f) awarding Relator his litigation costs and reasonable attorneys' fees; and
- (g) granting such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Relator hereby respectfully demands trial by jury on all issues and counts triable as of right before a jury.

Dated: 10/23, 2017

Respectfully submitted,


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